EXHIBIT A



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December 19, 2013

Certified Mail Return Receipt Requested 7010 1670 0000 9480 1992

Mr. Ronald D. Croatti, President UniFirst Corporation 68 Jonspin Rd Wilmington, MA 01887

RE: <u>Guzman, et al. v. New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, et al., C.A. No 12-cv-12208 (D. Mass.)</u>

Dear Mr. Croatti:

Our firm represents the plaintiffs, Mrs. Kathleen Guzman and Mr. Miguel Guzman, in the above referenced matter. Mrs. Guzman received an injection of contaminated preservative free methylprednisolone acetate ("MPA") that was compounded by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") at its facilities at 697 Waverly Street in Framingham, Mass. UniFirst Corporation, through its operating segment or division known as UniClean Cleanroom Services ("UniFirst"), was responsible for cleaning and sanitizing the NECC facility, but UniFirst failed, *inter alia*, to properly perform those duties and failed to use reasonable care to prevent and eliminate contamination within the NECC facilities. This letter constitutes a demand upon UniFirst pursuant to Massachusetts General Laws, Chapter 93A, §9 ("Chapter 93A"). Please immediately provide a copy of this letter to UniFirst's insurance carrier.

Relevant Facts

In October 2011, Mrs. Guzman obtained treatment for her ongoing back pain at Premier Orthopaedic Associates of Southern New Jersey, LLC d/b/a Premier Orthopaedic Associates Surgical Clinic, LLC, in Vineland, New Jersey, ("Premier"). On August 16, 2012, Mrs. Guzman received an epidural injection of MPA as part of that treatment. Her treating physician at Premier performed the procedure at Inspira Medical Center Vineland f/k/a South Jersey Healthcare Regional Medical Center ("Inspira"). The MPA injected into Mrs. Guzman's back was compounded and distributed by NECC from their Framingham, Massachusetts facility.

MPA is a steroid that is administered via epidural injection to patients suffering from back and/or neck pain. Until October 2012, NECC compounded MPA at its facility in Framingham, Massachusetts, and NECC compounded, marketed, sold and distributed tens of thousands of vials of MPA to healthcare providers across the country, including Premier and Inspira facilities in New Jersey.

Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the cleanroom utilized for the production of MPA. NECC and UniFirst knew or should have known of these findings. NECC and UniFirst failed to investigate those isolates and made no effort to identify those isolates, and NECC and UniFirst further failed to take any corrective actions with regards to the isolates which were found. Despite those findings, NECC continued to compound, market, sell and distribute MPA.

On September 21, 2012, the Centers for Disease Control and Prevention (the "CDC") was notified by the Tennessee Department of Health of a patient with the onset of meningitis, later determined to be fungal meningitis, following an epidural injection.

On its website, CDC explains that "fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus" and that "fungal meningitis is rare and usually the result of spread of a fungus through blood to the spinal cord." According to the CDC, symptoms for meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis. The symptoms of fungal meningitis, according to the CDC, "are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms."

In late September 2012, NECC recall the following lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012 and Lot #08102101@51, BUD 2/6/2013. NECC identified both Premier and Inspira as healthcare facilities that received vials of the MPA that were part of the September 2012 recall.

On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts." In its October 6 press release, NECC advised that is was "notifying its customers of this recall by fax" and that "clinics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice."

On October 5, Mrs. Guzman received a phone call from her medical providers and was

told that the injection she received on August 16, 2012, might have been contaminated with a fungus. The MPA that was injected into Mrs. Guzman's back came from one of the three lots of contaminated MPA recalled September 2012. Since August 16, 2012, Mrs. Guzman has experienced symptoms of meningitis, including headaches, neck pain, dizziness, disorientation, nausea and light sensitivity.

On October 5, 2012 went to the emergency room at Inspira as instructed in the call, but was not diagnosed at that time and was told to return immediately should her symptoms worsen. A few weeks later, on Halloween night Mrs. Guzman's symptoms worsened significantly and she returned to the Inspira emergency room and was admitted, underwent a painful lumbar puncture procedure, was diagnosed with fungal meningitis and began treatment with potent intravenous and oral antifungal medication. She returned to the fungal meningitis clinic at Inspira for months, periodically undergoing various diagnostic procedures including additional lumbar punctures to evaluate her ongoing fungal meningitis treatment. As this health crisis has developed over the past year, the CDC has published reports of relapse in many patients even after completing one or more lengthy rounds of aggressive antifungal treatment

It is believed that the aspergillus fungus was one of the types of fungus found in the contaminated MPA injected into Mrs. Guzman in August 2012. These fungi can produce toxins, exposure to which can cause cancer, strokes and allergies in exposed individuals.

Liability

UniFirst holds itself out as a service provider delivering value-added services and products to, among other industries, the medical device, pharmaceutical, and other industries that utilize cleanroom controlled environments. UniFirst represents that it offers comprehensive cleanroom cleaning and maintenance programs to help ensure that facilities are operating within specified classification criteria. UniFirst touts its expertise to companies like NECC.

UniFirst knows that particulates in cleanrooms are deposited onto surfaces such as floors, walls, work surfaces and machinery, and that these particulates may cause increases in manufacturing and product compounding reject rates. UniFirst, its agents, employees, representatives, and UniClean workers have, for many years, had actual knowledge that visible and non-visible particulate loads can also lead to product contamination safety concerns for end users. In its marketing materials UniFirst acknowledges that to reduce these risks, it is imperative that an effective cleanroom cleaning program be implemented and maintained. UniFirst claims to follow stringent cleaning procedures and claims to employ highly-trained technicians as key components in eliminating such contamination threats.

At all times mentioned herein and material hereto, UniFirst held itself and its agents, servants, workers, representatives, personnel, and employees out to be skillful and qualified to deliver quality services and products and through the highest standards.

Indeed, UniFirst represents that it is an ISO 9001:2008 registered company offering services that include sterile and non-sterile garment services, and contamination control including cleanroom cleaning, fogging and environmental monitoring, among other services.

UniFirst recognizes the dangers associated with contaminated cleanrooms. In the company's own marketing materials, it acknowledges that "80% of the dirt and grime that enters your building is tracked in on the shoes of employees and visitors." UniFirst knows that any contract for services or products entered into with any company such as NECC has a direct benefit for customers, who are the intended beneficiaries of such contracts. For example, UniFirst has stated on its website and in marketing materials that over 70% of customers say that a poorly maintained facility "is enough reason not to patronize a business again," and that by hiring UniFirst, a company's "business image will remain spotless, and your customers and employees will know you care."

UniFirst markets its products and services aggressively, and represents that, among other things, "to help with your infection control efforts, UniFirst delivers fresh mops and wipers and picks up you soiled ones on a regular schedule. We maintain inventory, perform hygienic laundering, and replace any worn out items."

Upon information and belief, UniFirst entered into a service agreement with NECC for contamination control services in late 2008 which agreement was renewed and continuing with full force and effect up to the time the NECC facility was closed in October 2012. The specific contamination control duties were set forth in detail in the service agreement schedule, describing the frequency, level of sanitization, and surfaces and rooms / areas to be cleaned. UniForce agreed to train the cleaning staff in clean room operating procedures, including the specific NECC clean room standard operating procedures, and supplied all materials and products utilized in carrying out these duties. UniForce employees, contractors and/or representatives failed to meet its own written standards in performing the contractual duties, allowing contamination of the cleanrooms it was entrusted to clean by allowing introduction of uncovered street clothing and shoes, uncovered hair and hands, unclean / unprocessed equipment and supplies moved from less clean areas exterior to the clean rooms into the clean rooms without proper cleaning / processing thereby allowing contaminants into and throughout the NECC facility.

UniFirst had actual knowledge of the dangers of bacteria, mold and other microorganisms. UniFirst knew or should have known that such contaminants – if not removed – would expose the end use customers, such as Mrs. Guzman, to contamination of products produced by NECC in its cleanrooms. Indeed, UniFirst had actual knowledge of the very mold that was ultimately found in the NECC facility. In a "white paper" found on the www.unifirst.com website, UniFirst identifies aspergillus niger as a "mold" that grows when garments are contaminated. In the white paper, UniFirst acknowledges that this mold represents one of the most common types of microorganism contaminants found in facilities like the NECC location.

UniFirst allowed dangerous contaminants into, and failed to eliminate those dangerous contaminants from, NECC's facilities. For instance, between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the cleanroom used for production of MPA. Moreover, Aspergillus niger was found and/or brought into the NECC facilities. UniFirst, its agents, and employees knew or should have known of the dangers of allowing contaminants into NECC's facilities, including its anterooms and cleanrooms.

Unless UniFirst offers a reasonable settlement amount to resolve this matter, Mrs. Guzman and her husband intend to amend their complaint to add claims against UniFirst pursuant to Chapter 93A based on the facts as summarized above.

<u>Damages</u>

A plaintiff who has suffered physical injury through the fault of a defendant is entitled to recover for pain and suffering; for reasonable expenses incurred by him for medical care and nursing in the treatment and cure of his injury; for diminution in his earning power; and for such pain and suffering and such expenses and diminution of earning capacity as are shown to be reasonably probable to continue in the future. The measure of damages is fair compensation for the injury sustained.

Rodgers v. Boynton, 315 Mass. 279, 280 (1943). Accord Donovan v. Philip Morris USA, Inc., 455 Mass. 215, 221 (2009).

With respect to Chapter 93A claims, the following relief is provided:

recovery shall be in the amount of actual damages . . . or up to three but not less than two times such amount if the court finds that the use or employment of the act or practice was a willful or knowing violation of said section two or that the refusal to grant relief upon demand was made in bad faith with knowledge or reason to know that the act or practice complained of violated said section two.

Mass. G. L. c. 93a, §9(4).

As a consequence of being injected with the contaminated MPA, Mrs. Guzman has incurred thousands of dollars in medical expenses. Further, given the fungal contamination and the resultant fungal meningitis, Mrs. Guzman will need long-term monitoring for relapse that is a foreseeable consequence of her exposure.

Aside from the expenses incurred, Mrs. Guzman has experienced a great deal of pain, anxiety and distress as a result of the many months testing and treatment of her fungal meningitis, and an extreme disruption of the enjoyment of her life. In addition Mrs. Guzman's pain and anxiety has adversely affected her relationship with her husband,

and consequently, Mr. Guzman has suffered a loss of consortium.

Please be advised that if UniFirst fails to respond with a good faith offer of settlement within thirty (30) days of receipt of this letter, the Court may find additional violations of Chapter 93A and award reasonable attorney's fees and multiple damages of up to three times the actual damages found at trial. See Mass. G.L.c. 93A, § 9(3).

Conclusion

Pursuant to Massachusetts General Law, Chapter 93A, § 9, demand is made to UniFirst to make a reasonable offer of settlement within thirty (30) days of the date of this letter.

If you have any questions or concerns, please feel free to contact our office.

John C. Thornton

Sincerely,

ANDREWS & THORNTON

JCT/mg



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December 20, 2013

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VIA CERTIFIED MAIL. R.R. 7010 1670 0000 9480 2012

Kimberly Smith-Martin, M.D. 298 S. Delsea Dr. Vineland, NJ 08360

RE: Notice of Intent to Commence Medical Malpractice Action

Dear Dr. Smith-Martin,

The alleged acts include all interactions between defendants and NECC in connection with the purchase and administration of drugs including during the year 2012. This letter serves as formal notice of Kathleen Guzman intent to file a lawsuit against you in court, pursuant to N.J.S.A. 2A:53A-26–29, for medical negligence, fraud, civil conspiracy, negligent purchasing of medications using false prescriptions, and lack of informed consent.

Factual Background

Kathleen Guzman was at the alleged times a patient of undergoing medical care and treatment from Defendants.

In a time frame believed to cover approximately May 21, 2012, through September 30, 2012, defendants negligently purchased on or about 1166 vials from three lots of contaminated preservative-free MPA from NECC. On September 16, 2012, Dr. Kimberly Smith-Martin performed a therapeutic facet injection of MPA, purchased from NECC. The MPA was contaminated with a fungus, *Exserohilum rostratum*.

Negligent Violation of Law, Civil Conspiracy, and Deceitful practices

Based on ordering patterns of defendant's office, the defendants purchased the MPA vials in bulk from NECC, in violation of Massachusetts and New Jersey law. Based on the investigation of the Massachusetts Board of Pharmacy and the investigation by CBS News in the 60 Minute investigation of NECC, it is likely that defendants engaged in a conspiracy with NECC including the submission of false or random names on prescription orders, and the writing of false and misleading prescriptions.

Medical Negligence

In the context of NECC's practice of suggesting, encouraging, and conspiring with customers, including defendants, to engage in false and deceptive prescription practices, it was a breach of professional standards of care for defendants not to take steps to investigate and protect patients from a compounder engaged in disreputable practices. Defendants failed to purchase a safer commercial methylprednisolone such as Solu-Medrol. If a decision was made to purchase compounded methylprednisolone, defendants breached their duty by failing to perform reasonable due diligence before purchasing. Defendants failed to select a Compounding pharmacy accredited by the Pharmacy Compounding Accreditation Board (PCAB). PCAB certification has been acknowledged to be an important gauge of safety by the American Medical Association. Defendants further breached their duty by failure to investigate the internal controls and quality assurance of NECC, to make certain that they were compliant with United States Pharmacopeia Standards (USP). Had defendants performed such an investigation they would have discovered that NECC was not compliant with USP, which would have caused a reasonable person in the defendants' position, within the applicable standard of care, to immediately stop using NECC products.

Lack of informed Consent

Before performing the ESI procedure on Kathleen Guzman on September 16, 2012, neither Dr. Smith-Martin, and/or Premier nor Inspira informed Ms. Guzman that the steroid that was to be injected into her spinal canal was not a medication manufactured by an FDA approved and inspected manufacturer, but rather was compounded by an unaccredited Massachusetts pharmacy that was not inspected by the FDA. Had Kathleen Guzman known these facts, as a reasonable person, she would not have consented to the injection.

As a result of the careless and deceptive practices of defendants discussed herein, defendants purchased contaminated drugs from NECC and injected them into patients including Victoria Gibson.

As a result of receiving the contaminated injections, Kathleen Guzman sustained and suffered injury to her body. She was admitted to the Inspira Regional Medical Center, f/k/a South Jersey Healthcare Regional Medical Center ("Inspira") on November 1, 2012 where she was diagnosed with an infection caused by a contaminated

NECC injection. According to her medical records from Inspira, she was afflicted with fungal meningitis. The injection caused disability, pain and suffering, and other economic and non-economic damages. There is significant risk that the injection will be long lasting and recurrent.

Kathleen Guzman plans to initiate a medical malpractice action against you, seeking compensation for the injuries she has suffered and sustained as a result of your actions. Her husband plans to seek damages for the diminished capacity and loss of the marital support, aid, cooperation and companionship by virtue of his infection and illness.

If you wish any additional information about the allegations, you may inquire to our office.

Yours truly,

John C. Thornton, Esq.

Anne Andrews, Esq.

Karren Schaeffer, Esq.

JCT/tb



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VIA CERTIFIED MAIL. R.R. 7010 1670 0000 9480 2029

Inspira Medical Center Vineland f/k/a South Jersey Healthcare Regional Medical Center 1038 East Chestnut Vineland, NJ 08360

RE: Notice of Intent to Commence Medical Malpractice Action

Dear Inspira Medical Center Vineland and any physicians and or pharmacists with responsibility for the formulary of the clinic and/or the orders for medication (collectively "defendants") from the New England Compounding Pharmacy in Framingham, Massachusetts aka New England Compounding Center ("NECC").

The alleged acts include all interactions between defendants and NECC in connection with the purchase of drugs including during the year 2012. This letter serves as formal notice of Kathleen Guzman intent to file a lawsuit against you in court, pursuant to N.J.S.A. 2A:53A-26–29, for medical negligence, fraud, civil conspiracy, negligent purchasing of medications using false prescriptions, and lack of informed consent.

Factual Background

Kathleen Guzman was at the alleged times a patient of undergoing medical care and treatment from Defendants.

In a time frame believed to cover approximately May 21, 2012, through September 30, 2012, defendants negligently purchased on or about 176 vials from three lots of contaminated preservative-free MPA from NECC. On September 16, 2012, Dr. Kimberly Smith-Martin performed a therapeutic facet injection of MPA, purchased from NECC. The MPA was contaminated with a fungus, *Exserohilum rostratum*.

Negligent Violation of Law, Civil Conspiracy, and Deceitful practices

Based on ordering patterns of defendant's office, the defendants purchased the MPA vials in bulk from NECC, in violation of Massachusetts and New Jersey law. Based on the investigation of the Massachusetts Board of Pharmacy and the investigation by CBS News in the 60 Minute investigation of NECC, it is likely that defendants engaged in a conspiracy with NECC including the submission of false or random names on prescription orders, and the writing of false and misleading prescriptions.

Medical Negligence

In the context of NECC's practice of suggesting, encouraging, and conspiring with customers, including defendants, to engage in false and deceptive prescription practices, it was a breach of professional standards of care for defendants not to take steps to investigate and protect patients from a compounder engaged in disreputable practices. Defendants failed to purchase a safer commercial methylprednisolone such as Solu-Medrol. If a decision was made to purchase compounded methylprednisolone, defendants breached their duty by failing to perform reasonable due diligence before purchasing. Defendants failed to select a Compounding pharmacy accredited by the Pharmacy Compounding Accreditation Board (PCAB). PCAB certification has been acknowledged to be an important gauge of safety by the American Medical Association. Defendants further breached their duty by failure to investigate the internal controls and quality assurance of NECC, to make certain that they were compliant with United States Pharmacopeia Standards (USP). Had defendants performed such an investigation they would have discovered that NECC was not compliant with USP, which would have caused a reasonable person in the defendants' position, within the applicable standard of care, to immediately stop using NECC products.

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John C. Thornton, Esq.

Anne Andrews, Esq.

Karren Schaeffer, Esq.

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VIA CERTIFIED MAIL. R.R. 7010 1670 0000 9480 2036

Premier Orthopaedic Associates of Southern New Jersey d/b/a Premier Orthopaedic Associates Surgery Center 298 S. Delsea Dr. Vineland, NJ 08360

RE: Notice of Intent to Commence Medical Malpractice Action

Dear Premier Orthopaedic Associates of Southern New Jersey and any physicians and or pharmacists with responsibility for the formulary of the clinic and/or the orders for medication (collectively "defendants") from the New England Compounding Pharmacy in Framingham, Massachusetts aka New England Compounding Center ("NECC").

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